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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/748,999	12/29/2003	Rozalina Dimitrova	17638 (BOT)	8259

7590 08/30/2006

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EXAMINER
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HUH, BENJAMIN

ART UNIT	PAPER NUMBER
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3767

DATE MAILED: 08/30/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

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<b>Office Action Summary</b>	<b>Application No.</b> 10/748,999	<b>Applicant(s)</b> DIMITROVA ET AL.	
	<b>Examiner</b> Benjamin Huh	<b>Art Unit</b> 3767	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 26 June 2006.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-3, 5, 7-10 and 15-20 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-3, 5, 7-10, 15-20 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>6/22/06</u> . | 6) <input type="checkbox"/> Other: _____  |

## DETAILED ACTION

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3, 5, & 7-10 are rejected under 35 U.S.C. 102(b) as being anticipated by Hsia (US Patent No. 4736526). The Hsia reference discloses a guide 17 in figure 1 comprising a material having an upper face and a lower face, the lower face of the material being suitable for placement in contact with an area of the dermis of a patient to or through which dermal area a botulinum toxin can be administered, and the material having a plurality of staggered perforations 19 which extend completely through the material from the upper face to the lower face, wherein the staggered perforations are spaced apart by a uniform distance, the material is flexible, so that when the material is pressed against the dermal area, substantially all of the lower face of the material is in contact with the dermal area since the device is made of a clear plastic that would inherently be able to flex in order to contact portions of the dermal area, and wherein the device is fully capable of being an injection guide for assisting administration of a botulinum toxin due to it's size, shape, and ability to work in the environment.

With respect to claims 7-10, wherein the material comprises a plurality of circles, seen as the borders of the perforations, and wherein they are deemed to be contiguous

since the definition of contiguous is "very close or next to" and wherein the circles are deemed to be "very close" or "next to" each other, also wherein the perforations are located in the center of the circles since the border of the perforations outline the circle.

Claims 1-3, 5, 7-10 are rejected under 35 U.S.C. 102(b) as being anticipated by Williamson (US Patent No. 4580561). The Williamson reference discloses a guide in figures 1 & 3 comprising a material having an upper face and a lower face, the lower face of the material being suitable for placement in contact with an area of the dermis of a patient to or through which dermal area a botulinum toxin can be administered, and the material having a plurality of staggered perforations 38 which extend completely through the material from the upper face to the lower face, wherein the staggered perforations are spaced apart by a uniform distance, and wherein the device is fully capable of being an injection guide for assisting administration of a botulinum toxin due to it's size, shape, and ability to work in the environment.

With respect to claims 3 & 5, wherein the material is deemed to be flexible since the degree of flexibility is not disclosed and claimed therefore if the material is capable of being flexed then the material is deemed flexible. Also, so when the material is pressed against the dermal area substantially all of the exterior border is in contact with the dermal area since when the material is pressed against the skin a large portion of the border will be in contact with the dermal area.

With respect to claims 7-10, wherein the material comprises a plurality of circles, seen as the borders of the perforations, and wherein they are deemed to be contiguous

since the definition of contiguous is "very close or next to" and wherein the circles are deemed to be "very close" or "next to" each other, also wherein the perforations are located in the center of the circles since the border of the perforations outline the circle.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 16, 18, 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hsia or Williamson as applied to claims 1, 5, & 10. Now even though the references do not explicitly disclose the use of 40, 60, or 80 perforations it would be an obvious design choice to alter the amount of perforations in order to provide a larger or more precise guide for Williamson or to allow a larger range for Hsia.

Claims 15, 17, & 19, are rejected under 35 U.S.C. 103(a) as being unpatentable over Hsia or Williamson. Now even though the references do not explicitly disclose the perforations to have a space of 1.5 or 2.0 cm between each other it would be an obvious design choice to do so in order to alter the range of the circles made with respect to Hsia and with location determination range with respect to Williamson, also wherein it would have been obvious to one having ordinary skill in the art at the time the invention was made to have a space of 1.5 or 2.0 cm, since it has been held that where

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the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

### ***Response to Arguments***

Applicant's arguments with respect to claims 1-3, 5, & 7-10 have been considered but are moot in view of the new ground(s) of rejection.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Benjamin Huh whose telephone number is 571-272-8208. The examiner can normally be reached on M-F: 9:00 AM - 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on 571-272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

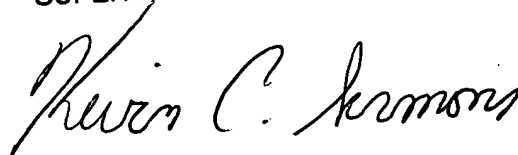
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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

BHH

BHH

KEVIN C. SIRMONS  
SUPERVISORY PATENT EXAMINER

A handwritten signature in black ink, reading "Kevin C. Sirmons", written over the printed name and title.